UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,730	12/30/2003	Thomas W. Wilson	WRL-004FOR	7530

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EXAMINER
FLEISCHER, MARK A

ART UNIT	PAPER NUMBER
3624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	10/748,730	WILSON, THOMAS W.
	Examiner	Art Unit	
	MARK A. FLEISCHER	3624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _23 July 2008_.
2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1 - 5, 9, 11 - 20, 23, 25 - 28 and 30 - 36_ is/are pending in the application.
    4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) _1 - 5, 9, 11 - 20, 23, 25 - 28 and 30 – 36_ is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on _23 July 2008_ is/are: a)☒ accepted or b)☐ objected to by the Examiner.
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    a)☐ All   b)☐ Some * c)☐ None of:
      1.☐ Certified copies of the priority documents have been received.
      2.☐ Certified copies of the priority documents have been received in Application No. _____.
      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .
5)☐ Notice of Informal Patent Application
6)☐ Other: _____.

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DETAILED ACTION

Status of Claims

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1. This action is in reply to the Amendments filed on 23 July 2008.

2. Claims 1 - 5, 11 - 16, 19, 20, 26 - 28 and 30 – 36 have been amended.

3. Claims 6 - 8, 10, 21, 22, 24, 37 and 38 have been canceled.

4. Claims 1 - 5, 9, 11 - 20, 23, 25 - 28 and 30 – 36 are currently pending and have been examined.

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Response to Amendments

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5. The rejection of claims 1, 14, 16 and 31 under 35 USC §112, 2nd paragraph are withdrawn in light of Applicant's amendments.

6. Examiner acknowledges Applicant's Terminal Disclaimer and withdraws the provisional rejections based on non-statutory double patenting with respect to co-pending application 10/693790.

7. The objections to the drawings are withdrawn in light of new drawings accompanying the amendments.

8. The objections to the specification is withdrawn in light of Applicant's amendments thereto.

9. The rejection of claims 4 - 8, 19 - 22 and 24 under 35 USC §112, 2nd paragraph are withdrawn in light of Applicant's amendments and/or cancellations as noted above.

10. The rejection of claims 37 - 38 under 35 USC §101 are withdrawn in light of Applicant's amendments and/or cancellations as noted above. The rejection of claim 36 however is maintained for the reasons set forth below.

11. The rejection of claim 36 under 35 USC §102(a) is withdrawn in light of Applicant's amendments which necessitated new grounds of rejections as set forth below.

12. The rejection of claim 37 under 35 USC §102(b) is withdrawn in light of Applicant's cancellation of this claim.

Response to Arguments

13. Applicant's arguments received on 23 July 2008 have been fully considered but they are not persuasive. Referring to the previous Office action, Examiner has cited relevant portions of the references as a means to illustrate the systems as taught by the prior art. As a means of providing further clarification as to what is taught by the references used in the first Office action, Examiner has expanded the teachings for comprehensibility while maintaining the same grounds of rejection of the claims, except as noted above in the section labeled "Status of Claims." This information is intended to assist in illuminating the teachings of the references while providing evidence that establishes further support for the rejections of the claims.

14. With respect to the rejection of claim 36 under 35 U.S.C. §101, Applicant claims that "the Output Expression is a physical object" presumably because it *may* be tangibly embodied on a physical medium and is a representation of information, but such expressions are not amenable to patent protection. An expression, as used in the application, is not an apparatus or article of manufacture; nor does it fall within the ambit of any other statutory category under section 101 which provide clear categories of patentable subject matter: "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof ..." Like an abstract idea or equation or formula or law of nature, the mere expression and physical embodiments thereof do not constitute patentable subject matter. Expressions themselves are amenable to copyright protection just as physically embodied sculptures or paintings are. While a method that produces a useful result may be patentable, the useful result where it is an expression, a rendering, etc. in and of itself is not.

15. In response to Applicant's argument that there is no teaching, suggestion or motivation to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references

themselves or <u>in the knowledge generally available to one of ordinary skill in the art</u>. See *In re Fine,* 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones,* 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

16. To this end, the Examiner recognizes that references cannot be arbitrarily altered or modified and that there must be some reason why one skilled in the art would be motivated to make the proposed modifications. Although the motivation or suggestion to make modifications must be articulated, it is respectfully submitted that there is <u>no requirement</u> that the motivation to make modifications must <u>be expressly articulated</u> <u>within the references themselves</u>. References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek,* 163 USPQ 545 (CCPA 1969). Thus, the issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re Delisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine,* 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu,* 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Moreover, it was determined in *In re Lamberti* et al 192 USPQ 278 (CCPA) that:

    (i) obvious does not require absolute predictability;

    (ii) non-preferred embodiments of prior art must also be considered; and

    (iii) the question is not express teaching of references but what they would suggest.

17. According to *In re Jacoby,* 135 USPQ 317 (CCPA 1962), the skilled artisan is presumed to know something more about the art than only what is disclosed in the applied references. Within *In re Bode,* 193 USPQ 12 (CCPA 1977), every reference relies to some extent on knowledge of persons skilled in the art to complement that which is disclosed therein. In *In re Conrad* 169 USPQ 170 (CCPA), obviousness is not based on express suggestion, but what references taken collectively would suggest.

1. In the instant case, and despite the very well articulated arguments of the Applicant, the Examiner finds Applicant's arguments unpersuasive and respectfully notes that each and every motivation to combine the applied references is accompanied by select portions of the respective references

which specifically support that particular motivation. As such, it is NOT seen that the Examiner's combination of references is unsupported by the applied prior art of record. Rather, it is respectfully submitted that explanation based on the logic and scientific reasoning of one ordinarily skilled in the art at the time of the invention that support a holding of obviousness has been adequately provided by the motivations and reasons indicated by the Examiner, *Ex pane Levengood* 28 USPQ 2d 1300 (Bd. Pat. App. & Inter., 4/22/93).

2. With regard to the limitations of pending claims 1-38, Applicant argues that McCartney fails to teach the "the step of forming at least one Cohort time segment based on the Start Time" (Remarks, p. 27). As noted by Applicant however that the Examiner states that the "first available date of enrollment and a time window is defined to provide a timeframe from which to judge whether events should be considered in subsequent processing. Accordingly, it appears that the Examiner believes that the "time window" is equivalent to a Cohort time segment." (Remarks, p. 27). Applicant further maintains that the notions of "a time window" as taught in Wong compared to the "Cohort time segment" of the Applicant are "profoundly different" (Remarks, p. 27) and, further, that the associated criteria as to whether an entity is included into a cohort is "arbitrary [*sic*] assigned by the operator" (Remarks, p. 28). This latter however misconstrues how the 'start time' is determined in Wong. Although some aspects of it are determined 'arbitrarily' as in "B can be selected somewhere in between..." (Wong [14,3-4]), other aspects of the time window determination and inclusion in a cohort are based on specified criteria. Specifically, the time point A "is defined based on the data extraction protocol... and C is defined by the last day for which the member is still enrolled and eligible for the benefits." (Wong, [14,5]). Moreover, the definition of time point B in Wong is specifically amenable to "alternative definitions [that] may also be used." (Wong [14,16]). Such time windows and time frames are based on information in data files such as "Date of first CHF diagnosis...Date of first CHF hospitalization...Date of first diabetes event..." (Wong [8,51-55]). These are examples of the many types of longitudinal and cohort statistical studies that are based on what are analogous to the instant "cohort time". Indeed, the establishment of relevant time frames based on membership criteria for inclusion in a cohort as

the basis of statistical analyses is old and well-known, especially in the medical arts and sciences

where the progression of disease, effectiveness of drug regimens and so forth are studied.

18. In summary, the Examiner has taken the broadest and most reasonable interpretation of the

claim limitations *as written*, in light of the specification. Although the specification may contain

recitations of intended use, alternative points of view and subjective interpretative differences

between the prior art of record and the present invention as premeditated, it is the claims

themselves that are given patentable weight only inasmuch as they are constructed.

19. Regarding claims 34, , Applicant has failed to rebut Examiner's **Official Notices** that

- utilizing computer systems comprising a central processing unit along with system software to

  perform method or algorithmic steps or procedures in data intensive environments,

- employing the use of various types of stratified sampling techniques,

were old and well known in the art at the time of the invention. Examiner notes the following

discussion of **Official Notice** taken from the MPEP:

> To adequately traverse such a finding, an applicant must specifically
> point out the supposed errors in the examiner's action, which would
> include stating why the noticed fact is not considered to be common
> knowledge or well-known in the art. See 37 CFR 1.111(b). See also
> *Chevenard, 139 F.2d at 713, 60 USPQ at 241* ("[I]n the absence of any
> demand by appellant for the examiner to produce authority for his
> statement, we will not consider this contention."). A general allegation
> that the claims define a patentable invention without any reference to the
> examiner's assertion of official notice would be inadequate. If applicant
> adequately traverses the examiner's assertion of official notice, the
> examiner must provide documentary evidence in the next Office action if
> the rejection is to be maintained. See 37 CFR 1.104(c)(2). See also
> *Zurko, 258 F.3d at 1386, 59 USPQ2d at 1697* ("[T]he Board [or
> examiner] must point to some concrete evidence in the record in support
> of these findings" to satisfy the substantial evidence test). If the examiner
> is relying on personal knowledge to support the finding of what is known
> in the art, the examiner must provide an affidavit or declaration setting
> forth specific factual statements and explanation to support the finding.
> See 37 CFR 1.104(d)(2). If applicant does not traverse the examiner's
> assertion of official notice or applicant's traverse is not adequate, the
> examiner should clearly indicate in the next Office action that the
> common knowledge or well-known in the art statement is taken to be
> admitted prior art because applicant either failed to traverse the
> examiner's assertion of official notice or that the traverse was
> inadequate. If the traverse was inadequate, the examiner should include
> an explanation as to why it was inadequate. (MPEP § 2144.03(C))

Applicant has not "specifically point[ed] out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art." Applicant statements do not amount to a sufficient traversal because no such statements were proffered. For these reasons,

- utilizing computer systems comprising a central processing unit along with system software to perform method or algorithmic steps or procedures in data intensive environments,

- employing the use of various types of stratified sampling techniques,

is taken to be admitted prior art.

Claim Objections

20. Claims 1 and 34 objected to because of the following informalities: The claims contain grammatical errors: "identifying at least one criteria" should read "identifying at least one criterion". Appropriate correction is required.

Claim Rejections - 35 USC § 101

21. 35 U.S.C. §101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

22. Claims 36 is rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. The claim refers to an expression for which patent protection is sought. Expressions, physically embodied or not does not constitute "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof ..." Therefore, expressions, as noted above, are not amenable to patent protection under this statute.

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Claim Rejections - 35 USC § 103

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23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. Claims 1 - 5, 9, 11 - 20, 23, 25 - 28 and 30 – 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCartney (PG-Pub 2003/0065534 A1), in view of Wong (US 5,976,082 A).

Claims 1 and 34:

McCartney, as shown, discloses and/or describes the following limitations:

- *A method of improving resource allocation* (McCartney [0002]: "…and allows for optimized allocation of health care resources.") *comprising the steps of:*
  - *identifying at least one criteria;*
  - *identifying sets of information wherein each set of information includes*
    - *a UOA-ID* (Applicant on page 9, line 22: …*means the particular individual UOA entity involved in the study* and further provides examples on page 10, line 2 as *patients having a common diagnosis or condition…* McCartney [0039] also describes a Patient Group: "…for example all patients who had a simple appendectomy are in a Patient Group."),
    - *a CCT* (Applicant on page 9, line 17 refers to *calendar clock date/time.* McCartney [0003] refers to dynamic periods of time for given situations: "For example a person admitted to a hospital [ ] will generally require operating room time, recovery ward time…" (emphasis added) and further describes in [0004] patients that must be "tracked virtually on a real time basis" (emphasis added)) *and a*

- • *VAR Value* (Applicant on page 10, line 21 defines *VAR*. McCartney, in at least [0064-5] also refers to various values associated with resource allocation decisions and modules that determine them: "generating the case cost profile rather than the adjusted values.");

- – *grouping each UOA-ID into an appropriate Type* (Applicant defines *Type* on page 10, line 8. McCartney in at least [0026] describes this same limitation: "the grouping systems in different countries generally use the same approach to grouping disease and treatment case types." Emphasis added.);

McCartney does not specifically include the following limitations, but Wong, as shown does.

- – *identifying a Start Time wherein each UOA-ID has met said at least one criteria;* (Applicant defines the *start time* generally as the time at which group membership criteria are satisfied. Wong, in at least [0050] states: "First available date of enrollment (i.e., start of dataset or enrollment date) [ ] Date of first CHF diagnosis (ICD-9 code in any position)…");

- – *forming at least one prospective or retrospective Cohort time segment for each UOA-ID based on their Start Time* (Wong, in at least the abstract states: "A time window is defined to provide a timeframe from which to judge whether events should be considered in subsequent processing…" where 'time window' is equivalent to a *Cohort time segment*. Also, Wong [0013] relates such time windows to a specified plurality of variables to identify analysis and prediction regions. Thus, such time segments entertain those "risk groups" or other specified criteria.);

- – *placing the UOA-ID into the appropriate time segment* (Wong in at least [0013] states: "…the time window is used to identify an analysis region…" and in [0017] "…using the **time window** and the set of variables, to generate an **analysis** file…" The method of 'using the time window' is thus equivalent to the limitation in that the set of variables is associated with the particular time window. This association

corresponds to the relevant *UOA-ID* that is associated with *the appropriate time segment);*

    – *calculating an eligibility score for each UOA-ID for each time segment* (Applicant refers to *eligibility score* on page 14, line 17 as corresponding to the time-frame in which a unit of analysis is available for study both 'prospectively and retrospectively' and further provides an example where the score is given in terms of months. Wong, in at least [0161] describes the use of analysis weights associated with time windows: "…analysis weights which reflect proximity to the event to be predicted can be used, for example, within 3 months × 1, 3-6 months × 0.75 …");

McCartney, as shown, discloses and/or describes the following limitations:

    – *calculating an Eligible Adjusted Variable Value* (McCartney, in at least [0064-5] states: "…to reconcile [ ] case costing data available [ ], resulting in <u>adjusted cost</u> …" (emphasis added) where adjusted cost corresponds to *Adjusted Variable Value.*); *and*

    – *generating at least one Output Expression* (McCartney, in at least [0171] states: "<u>The output generated</u> by applying the model is a file containing a list of all of the CHF patients ordered by an indicator representative of the likelihood that that patient will have an adverse health outcome (i.e., experience that defined by the dependent variable). This list can then be <u>divided into subgroups</u> such as in 5% or 10% increments of patients likely to have the adverse health outcome…" (emphasis added) wherein the various groups corresponds to *eligible* data entities.)

With respect to claim 34, Examiner takes **Official Notice** that it is old and well-known as well as commonplace in the technical and medical arts to utilize computer systems comprising a central processing unit along with system software to perform method or algorithmic steps or procedures in data intensive environments. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to combine the resource allocation method of McCartney with Wong's recitation of time-dependent variables because each

pertain to the statistical analysis of health care systems and disease management issues and

seek to identify ways to improve the efficiency of healthcare delivery systems.

Claims 2 and 17:

McCartney/Wong disclose the limitations as shown in the rejections of claims 1 and 16 above.

McCartney as shown, further discloses and/or describes the following limitations:

- *The method of claim 1 further comprising the step of transforming the Output*

   Expressions from being expressed in Cohort time segments... (McCartney, in at least

   [0003], describes various types of *cohort time*: "They will generally require operating

   room **time**, recovery ward **time**...")

McCartney does not specifically include the following limitations, but Wong, as shown does.

   ...to being expressed in CCT segments (Wong, in at least claim 1, states a step which

   includes: "converting data representing the extracted claims information and the defined

   events into files containing event level information".   This conversion process is

   equivalent to a transformation of *cohort time segments* to *CCT segments* because CCT

   segments pertain to the times at which events occur.   Moreover, in at least [0048]

   specifically states "the information is converted into an event level format." Finally, in

   [0051], Wong states: "Primary data file 2 is an events level file with a record for each

   event ordered by member and the chronological date of the event, in the present

   invention, presented in descending order of event date." (emphasis added).)

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention

to combine the statistical methods of McCartney and Wong because translating time periods

associated with conditions to absolute or calendar time facilitates the ability of analysts to make

meaningful assessments of resource utilization and discern trends in the data.

Claims 3 and 18:

McCartney/Wong disclose the limitations as shown in the rejections of claim 1 above and 16

below. McCartney/Wong do not specifically disclose *wherein said method is performed using a*

system comprising a central processing unit for implementing system software effective for

performing the method. However, Examiner takes **Official Notice** that it is old and well-known as well as commonplace in the technical and medical arts to utilize computer systems comprising a central processing unit along with system software to perform method or algorithmic steps or procedures in data intensive environments. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to utilize a central processing unit along with system software because their use enables the practical utility by increasing the efficiency and reliability of the resource allocation system.

Claims 4, 5, 9 and 19–25, 35:

McCartney/Wong disclose the limitations as shown in the rejections of claim 1 (above), 16 (below) and 34 (above). The limitations in these claims recite intended use and so are not given patentable weight.

Claims 11 and 26:

McCartney/Wong disclose and/or describe the limitations of claim 1 and 16 above. McCartney further discloses and/or describes the following limitations:

- *The method of claim 1 wherein each Output Expression is generated by the method comprising the step of calculating an EAV based on a summary metric for each UOA-ID per Type* (McCartney, in at least [0064-5] states: "…to reconcile [ ] case costing data available [ ], resulting in <u>adjusted cost</u> …" (emphasis added) where adjusted cost corresponds to *Adjusted Variable Value.* McCartney, in at least [0070] states: "For each of the Patient Groups [… a column] [ ] that <u>identifies the average length of stay</u> (ALOS) associated per case per Patient Group." (emphasis added) where the 'average length…' corresponds to a *summary metric* for which a value is associated.)

Claims 12 and 27:

McCartney/Wong disclose and/or describe the limitations of claim 1 above and 16 below. Wong further discloses and/or describes the following limitations:

- *determining a DV per Type per time segment* (See Wong, in at least [0150]: "…this is a <u>dichotomous variable</u>…" (emphasis added) See also the rejection of claim 1 above and Examiner's **Official Notice** below);

- *calculating an EAV summary metric for all UOA-IDs per Type per time segment* (See the rejections of claim 11 above); *and*

- *calculating an EAV Net Value per Type per time segment* (See the rejections of claims 1 above. McCartney also specifically refers to 'total' resource use. For example, in at least [0005]: "[R]esearch has indicated that while length of stay can be a useful indicator of <u>total resource use</u>, it can be a misleading indicator for some case types and some resources." and in [0057] "<u>total consumption</u> information" and in [0063] "actual <u>total statistical unit usage</u>…" (emphasis added) and thus corresponds to a *<u>Net</u> Value per Type*.)

McCartney/Wong do not specifically describe the limitations regarding a *DV <u>per time segment</u>*, but, 'DV', being a 'dichotomous variable' (see page 27, lines 15-17) is simply a Boolean value that is used to stratify the data. Examiner's takes **Official Notice** that it is well known and commonplace in the statistical analysis arts to employ the use of various types of stratified sampling techniques. These strata are, by definition, mutually exclusive. Applicant employs the term 'DV' to define two mutually exclusive sets of values depending on the context which, in Wong, also involves a <u>time-based</u> aspect (see Wong in at least [0150]: "Resources counted from time of cost…"). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to use a Boolean technique for stratifying data in conjunction with the health care and disease management methods of McCartney and Wong because many types of data must be either included in an output analysis or excluded from it in order to make the analysis meaningful.

Claims 13 and 28:

McCartney/Wong disclose and/or describe the limitations of claims 1 above and 16 below. McCartney/Wong, as shown, further discloses and/or describes the following limitations:

- *determining a RORA* (Wong, in at least [0150] wherein "resource utilization is measured in dollars." 'Resource utilization' is thus equivalent to *return on resource allocation'* (RORA))*;*

- *determining an Outcome* (McCartney, in at least [0171] states: "The output generated by applying the model is a file […]" (emphasis added) where the 'output generated' corresponds to *determining an Outcome.);*

- *calculating a NNT* (Wong, in at least [0002] describes his invention in terms of "targeted interventions" relative to congestive heart failure patients and thus requires the determination of the *number needed to target (NNT).*)

- *calculating an EAV Net Value per Type per time segment* (See the rejection of claim 1 relative to the *EAV* calculation. Also, McCartney also specifically refers to 'total' resource use. For example, in at least [0005]: "[R]esearch has indicated that while length of stay can be a useful indicator of total resource use, it can be a misleading indicator for some case types and some resources." and in [0057] "total consumption information" and in [0063] "actual total statistical unit usage…" (emphasis added) and thus corresponds to a *Net Value per Type.); and*

- *calculating the maximum available RA per UOA-ID per time segment* (See the rejection of the limitation above regarding *RORA*. Note, that McCartney, in at least [0053], refers to "relative resource weightings" in which it is fairly implied that a weighting of 1 corresponds to the maximum weight, hence corresponds to the instant limitation.)

Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to combine the resource allocation method of McCartney with Wong's recitation of time-dependent variables because each pertain to the statistical analysis of health care systems and disease management issues and seek to identify ways to improve the efficiency of healthcare delivery systems.

Claims 14 and 29:

McCartney/Wong disclose and/or describe the limitations of claim 1 above and 16 below.

McCartney/Wong, as shown, further discloses and/or describes the following limitations:

- *determining a RA* (See the rejection of claim 13. Note, that McCartney, in at least [0053], refers to "relative resource weightings" in which it is fairly implied that a weighting of 1 corresponds to the maximum weight, hence corresponds to the instant limitation.)*;*

- *determining an Outcome* (McCartney, in at least [0171] states: "<u>The output generated by applying the model</u> is a file [...]" (emphasis added) where the 'output generated' corresponds to *determining an Outcome*.)*;*

- *calculating a NNT* (Wong, in at least [0002] describes his invention in terms of "targeted interventions" relative to congestive heart failure patients and thus requires the determination of the *number needed to target (NNT)*.);

- *calculating an EAV Net Value per Type per time segment* (Also, McCartney also specifically refers to 'total' resource use. For example, in at least [0005]: "[R]esearch has indicated that while length of stay can be a useful indicator of <u>total resource use</u>, it can be a misleading indicator for some case types and some resources." and in [0057] "<u>total consumption</u> information" and in [0063] "actual <u>total statistical unit usage</u>..." (emphasis added) and thus corresponds to a <u>*Net* Value per Type</u>.)*; and*

- *calculating the RORA per UOA-ID per time segment* (See the rejection of claim 8. Note that claim 13 refers to *determining a RORA* whereas here, this calculation is based on stratified data. However, other limitation in claim 13 effectively addresses this stratification).

Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to combine the resource allocation method of McCartney with Wong's recitation of time-dependent variables because each pertain to the statistical analysis of health care systems and disease management issues and seek to identify ways to improve the efficiency of healthcare delivery systems.

Claims 15 and 30:

McCartney/Wong disclose and/or describe the limitations of claim 1 and 16 above. McCartney/Wong, as shown, discloses and/or describes the following limitations:

- *determining a RORA* (Wong, in at least [0150] wherein "resource utilization is measured in dollars." 'Resource utilization' is thus equivalent to *return on resource allocation'* (RORA))*;*

- *determining a RA* (McCartney, in at least [0053], refers to "relative resource weightings" in which it is fairly implied that a weighting of 1 corresponds to the maximum weight, hence corresponds to the instant limitation.)*;*

- *calculating a NNT* (Wong, in at least [0002] describes his invention in terms of "targeted interventions" relative to congestive heart failure patients and thus requires the determination of the *number needed to target (NNT).*);

- *calculating an EAV Net Value per Type per time segment* (McCartney, in at least [0064-5] states: "…to reconcile [ ] case costing data available [ ], resulting in <u>adjusted cost</u> …" (emphasis added) where adjusted cost corresponds to *Adjusted Variable Value.* Also, McCartney also specifically refers to 'total' resource use. For example, in at least [0005]: "[R]esearch has indicated that while length of stay can be a useful indicator of <u>total resource use</u>, it can be a misleading indicator for some case types and some resources." and in [0057] "<u>total consumption</u> information" and in [0063] "actual <u>total statistical unit usage</u>…" (emphasis added) and thus corresponds to a *<u>Net Value per Type</u>.); and*

- *calculating an Output per UOA-ID per time segment* (McCartney, in at least [0171] states: "<u>The output generated</u> by applying the model is a file containing a list of all of the CHF patients ordered by an indicator representative of the likelihood that that patient will have an adverse health outcome (i.e., experience that defined by the dependent variable). This list can then be <u>divided into subgroups</u> such as in 5% or 10% increments of patients likely to have the adverse health outcome…" (emphasis

added). Wong, in at least [0161] describes the use of analysis weights associated

with time windows: "...analysis weights which reflect proximity to the event to be

predicted can be used, for example, within 3 months × 1, 3-6 months × 0.75 ...").

Therefore, it would have been obvious to one with ordinary skill in the art at the time of the

invention to combine the methods of McCartney with the invention of Wong because they pertain

to the statistical analysis of health care systems and disease management issues and seek to

identify ways to improve the efficiency of healthcare delivery systems.

Claim 16:

McCartney, as shown, discloses and/or describes the following limitations:

- *A method for improving resource allocation using a plurality of sets of information*
  (See the preamble to the rejection of claim 1. Note also that *plurality of sets* is
  equivalent to *identifying sets of information* as in claim 1)*, the method comprising the
  steps of:*

- *for each set of information, identifying*

  - *an UOA-ID* (See the rejection of claim 1)*,*

  - *a Type* (McCartney, in at least [0026] describes a "classification system" where
    elements of defined groups must meet certain criteria for inclusion in the relevant
    group.)*,*

  - *a CCT* (See the rejection of claim 1) *and*

  - *a VAR Value* (See the rejection of claim 1)*;*

- *grouping each UOA-ID into an appropriate Grouper* (McCartney in at least [0030]
  refers to examples of groups and subgroups of patients. In [0026] McCartney
  specifically refers to "grouping systems" and thus corresponds to a *Grouper*.)*;*

- *placing each AdjVAR Value into the appropriate time segment* (McCartney in at least
  [0009] states: "a health care resource profiling system that includes a [ ] database [ ]
  quantifying a total use of a health care resource [ ] during a <u>predefined</u> <u>time</u> period..."

where the notion of 'predefined' circumscribes time segments, and *ipso facto* an

<u>appropriate</u> time segment.)*;*

- *calculating an eligibility score for each UOA-ID* (See the rejection of claim 1)*; and*

- *generating an Output Expression* (See the rejection of claim 1).

McCartney does not specifically include the following limitations, but Wong, as shown does.

- *identifying a Start Time wherein said Start time is the earliest CCT for each specific UOA-ID per Type* (See the rejection of claim 1. Wong [0156] also refers to a time window that starts at some particular point and in [0050] refers to the "First available date of enrollment (i.e., start of dataset or enrollment date)" which, in effect corresponds to the start time for a particular group or class of patients.)*;*

- *identifying a time segment duration* (Wong in at least [0167] refers to "length of stay")*;*

- *forming time segments based on the Start Time wherein each UOA-ID meet a certain eligibility criteria* (Wong in at least [0017] describes the acts of : "defining a <u>time window</u> for providing a timeframe" where 'defining' is equivalent to *forming...* Wong [0050] states: "First available date of enrollment (i.e., start of dataset or enrollment date) [ ] Date of first CHF diagnosis (ICD-9 code in any position)..." which corresponds to such eligibility criteria.)*;*

- *adjusting and standardizing each VAR Value to create AdjVAR Values* (See the rejection in claim 1 of the limitation component *VAR Value* that specifically mentions "adjusted values")*;*

Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to combine the resource allocation method of McCartney with Wong's recitation of time-dependent variables because each pertain to the statistical analysis of health care systems and disease management issues and seek to identify ways to improve the efficiency of healthcare delivery systems.

Claims 31, 32 and 33:

McCartney, as shown, discloses and/or describes the following limitations:

- *identifying at least one set of information each set comprising*

    - *a UOA, and a UOA-ID* (Applicant on page 9, line 22: ...*means the particular individual UOA entity involved in the study* and further provides examples on page 10, line 2 as *patients having a common diagnosis or condition...* McCartney [0039] also describes a Patient Group: "...for example all patients who had a simple appendectomy are in a Patient Group."),

    - *a Type* (McCartney, in at least [0026] describes a "classification system" where elements of defined groups must meet certain criteria for inclusion in the relevant group.),

    - *a CCT* (Applicant on page 9, line 17 refers to *calendar clock date/time.* McCartney [0003] refers to dynamic periods of time for given situations: "For example a person admitted to a hospital [ ] will generally require <u>operating room time,</u> <u>recovery ward time</u>..." (emphasis added) and further describes in [0004] patients that must be "tracked virtually on a real <u>time</u> basis"), *and*

    - *and a VAR Value* (Applicant on page 10, line 21 defines *VAR.* McCartney, in at least [0064-5] also refers to various values associated with resource allocation decisions and modules that determine them: "generating the case cost profile rather than the adjusted values.");

- *grouping each UOA-ID into an appropriate Type* (Applicant defines *Type* on page 10, line 8. McCartney in at least [0026] describes this same limitation: "the grouping systems in different countries generally use the same approach to <u>grouping disease and treatment case types.</u>" Emphasis added.);

- *placing the VAR Value into the appropriate time segment* (McCartney in at least [0009] states: "a health care resource profiling system that includes a [ ] database [ ] quantifying a total use of a health care resource [ ] during a <u>predefined time period</u>..." where the notion of 'predefined' circumscribes time segments, and *ipso facto* an <u>appropriate</u> time segment.);

- *calculating an Eligible Adjusted Variable Value* (McCartney, in at least [0064-5] states: "…to reconcile [ ] case costing data available [ ], resulting in <u>adjusted cost</u> …" (emphasis added) where adjusted cost corresponds to *Adjusted Variable Value.*);

- *and generating Output Expression* (McCartney, in at least [0171] states: "<u>The output generated</u> by applying the model is a file containing a list of all of the CHF patients ordered by an indicator representative of the likelihood that that patient will have an adverse health outcome (i.e., experience that defined by the dependent variable).

- The last limitations in each of these claims recite intended use and so are not given patentable weight.

McCartney does not specifically include the following limitations, but Wong, as shown does.

- *identifying a Start Time wherein each UOA-ID meets all of the eligibility criteria to be included into a Population* (Applicant defines the *start time* generally as the time at which group membership criteria are satisfied. Wong, in at least [0050] states: "First available date of enrollment (i.e., start of dataset or enrollment date) [ ] Date of first CHF diagnosis (ICD-9 code in any position)…");

- *forming at least one Cohort Time segment based on the Start Time* (Wong, in at least the abstract states: "A time window is defined to provide a timeframe from which to judge whether events should be considered in subsequent processing…" where 'time window' is equivalent to a *Cohort time segment.*);

- *calculating an eligibility score for each UOA-ID for each time segment* (Applicant refers to *eligibility score* on page 14, line 17 as corresponding to the time-frame in which a unit of analysis is available for study both 'prospectively and retrospectively' and further provides an example where the score is given in terms of months. Wong, in at least [0161] describes the use of analysis weights associated with time windows: "…analysis weights which reflect proximity to the event to be predicted can be used, for example, within 3 months × 1, 3-6 months × 0.75 …");

Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to combine the resource allocation method of McCartney with Wong's recitation of time-dependent variables because each pertain to the statistical analysis of health care systems and disease management issues and seek to identify ways to improve the efficiency of healthcare delivery systems.

Claim 36:

McCartney, as shown, discloses and/or describes the following limitations:

An Output Expression comprising a representation showing EAV trends of a particular Population [...], said trends are expressed in Cohort time segments [...] (Applicant on page 17, line 14 states that *EAV may be, but are not limited to, a quantity count, dollar value, number of products, and number of events, etc.* hence, correspond to a value of interest expressed in *Cohort time segments.* But a *cohort time segment* is the time segment a particular entity (unit of analysis) satisfies a given criterion. McCartney, in at least [0004] describes the burden of "track[ing] every resource that is used in respect of every patients by predetermined case types [ ] during the **time** that the patient is in the care of the health care provider." Thus, 'predetermined case types' associated with certain defined time periods corresponds to *cohort time segments* and the notion of <u>tracking resources used</u> is a form of *showing EAV trends.* Also, McCartney, in at least [0003] describes values and costs which correspond to *EAV* and describes trends which correspond to *cohort time trends*).

McCartney does not specifically teach that a particular population *having an eligibility criteria and formed from individual units each meeting at least one defined criteria,* and where the cohort time segments are *based on a Start Time wherein each individual unit meets all of the eligibility criteria to be included into the Population; a showing NNT trends of a particular Population; said trends are expressed in Cohort time segments.,* but Wong does and in at least [0050] states: "First available date of enrollment (i.e., start of dataset or enrollment date) [ ] Date of first CHF diagnosis (ICD-9 code in any position)..." which corresponds to such eligibility criteria. Wong [abstract] further refers to cohort time segments where individuals meet such eligibility criteria: "A

time window is defined to … judge whether events should be considered…", hence indicates

some criteria for judging whether information is proper for analysis, *i.e.,* eligible. Wong further

describes the 'number needed to target' in [0002] regarding "targeted interventions" relative to

congestive heart failure patients. Wong, in at least claim 1, states a step which includes:

"converting data representing the extracted claims information and the defined events into files

containing event level information". This conversion process is equivalent to a transformation of

cohort time segments to *CCT segments* because CCT segments pertain to the times at which

events occur. Moreover, in at least [0048] Wong specifically states "the information is converted

into an event level format." Finally, in [0051], Wong states: "Primary data file 2 is an events level

file with a record for each event ordered by member and the <u>chronological date</u> of the event, in

the present invention, presented in descending order of <u>event date</u>." (emphasis added).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention

to combine the statistical methods of McCartney and Wong because translating time periods

associated with conditions to absolute or calendar time facilitates the ability of analysts to make

meaningful assessments of resource utilization and discern trends in the data.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Mark A. Fleischer** whose telephone number is **571.270.3925.** The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **Bradley Bayat** whose telephone number is **571.272.6704** may be contacted.

The prior art made of record and not relied upon that is considered pertinent to applicant's disclosure are:

- Schloss, *et al.* (US 5692125 A) describes and/or discloses a system and methods to analyze resource allocation decisions where there are fixed and dynamic conditions.

- Geskus, R. "Methods for estimating the AIDS incubation time distribution when date of seroconversion is censored" (2001) describes use of cohort studies with respect to time-based events.

- Gordin, Fred, *et al.* "Early Manifestations of Disseminated Mycobacterium avium Complex Disease: A Prospective Evaluation" also describes use of cohort studies with respect to time-based events.

- Goggins, William, *et al.* "Applying The Cox Proportional Hazards Model For Analysis Of Latency Data With Interval Censoring" also describes use of cohort studies with respect to time-based events.

- Kim, S. *et al.* "Strategies for Cohort Sampling Under the Cox Proportional Hazards Model, Application to an AIDS Clinical Trial" also describes use of cohort studies with respect to time-based events.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair <http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks

P.O. Box 1450

Alexandria, VA 22313-1450

or faxed to **571-273-8300**.

Hand delivered responses should be brought to the **United States Patent and Trademark Office Customer Service Window**:

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      Mark A. Fleischer
/Mark A Fleischer/
Examiner, Art Unit 3624   6 December 2008

/Bradley B Bayat/
Supervisory Patent Examiner, Art Unit 3624